

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION**

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Case No. 1:22-cv-00061-TSK

JURY TRIAL DEMANDED

**PLAINTIFF REGENERON PHARMACEUTICALS, INC.’S ANSWER TO DEFENDANT
MYLAN PHARMACEUTICALS INC.’S FIRST AMENDED COUNTERCLAIMS**

Plaintiff and Counterclaim Defendant Regeneron Pharmaceuticals, Inc. (“Regeneron” and/or “Plaintiff”) hereby submits this Answer to the First Amended Counterclaims of Defendant and Counterclaimant Mylan Pharmaceuticals Inc. (“Mylan” and/or “Defendant”) (ECF 435, hereinafter “Counterclaims”).

Mylan’s Answer to Regeneron’s Complaint includes sixty-one separate affirmative defenses, to which no response is required. To the extent that a response is required, Regeneron denies the allegations in Mylan’s affirmative defenses and reserves the right to introduce evidence rebutting those allegations.

The paragraph number of each paragraph below corresponds to the same paragraph number in the Counterclaims. Regeneron denies each and every allegation in the Counterclaims, including without limitation allegations that appear in headings, subheadings, and footnotes, except as expressly admitted herein, and specifically denies that Defendant is entitled to the relief sought in its Prayer for Relief. Regeneron reserves the right to amend or supplement this Answer. Regeneron responds to the Counterclaims as follows:

PARTIES

1. Admitted upon information and belief.
2. Admitted.

JURISDICTION AND VENUE

3. Regeneron admits that Mylan purports to base its Counterclaims on the cited sections of the United States Code.

4. The allegations of Paragraph 4 are legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that the Court has subject matter jurisdiction over Mylan's Counterclaims solely for the purposes of this litigation.

5. Admitted.
6. Admitted.

BACKGROUND

7. Admitted.
8. Admitted.
9. Admitted upon information and belief.
10. Admitted.

BPCIA

11. Regeneron admits that the BPCIA provides a process through which an applicant may file an "abbreviated Biologics License Application" (aBLA), including a process for FDA review and potential approval of biosimilar products, and a process for resolving patent disputes that may arise with respect to such products. Regeneron further states that the BPCIA statute speaks for itself.

12. Regeneron admits that 42 U.S.C. § 262(k) describes the requirements for regulatory approval of a biological product. Regeneron further states that Paragraph 12 contains legal conclusions to which no response is required. Regeneron further states that the BPCIA statute speaks for itself.

13. Regeneron admits that Paragraph 13 quotes from a sentence from *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669 (2017), which speaks for itself. Regeneron further states that Paragraph 13 contains legal conclusions to which no response is required.

14. Regeneron admits that 42 U.S.C. § 262(k) describes the requirements for regulatory approval of a biological product, and that Paragraph 14 quotes portions of 42 U.S.C. § 262(i)(2) and 42 U.S.C. § 262(k)(2)(A)(i). Regeneron further states that Paragraph 14 contains legal conclusions to which no response is required. Regeneron further states that the BPCIA statute speaks for itself.

15. Regeneron admits that the BPCIA sets forth a process for resolving patent disputes that may arise with respect to biosimilar products, and that Paragraph 15 quotes from a sentence from *Sandoz*, 137 S. Ct. at 1670, which speaks for itself. Regeneron further states that Paragraph 15 contains legal conclusions to which no response is required. Regeneron further states that the BPCIA statute speaks for itself.

16. Regeneron admits that the BPCIA sets forth a process for resolving patent disputes that may arise with respect to biosimilar products, and that Paragraph 16 quotes portions of 42 U.S.C. § 262(l)(2)(A) and 42 U.S.C. § 262(l)(2)(B). Regeneron further states that Paragraph 16 contains legal conclusions to which no response is required. Regeneron further states that the BPCIA statute speaks for itself. To the extent that a further response is deemed required, Regeneron denies any remaining allegations of Paragraph 16.

17. Regeneron admits that the BPCIA sets forth a process for resolving patent disputes that may arise with respect to biosimilar products, and that Paragraph 17 quotes portions of 42 U.S.C. § 262(l)(1)(B)(i) and 42 U.S.C. § 262(l)(1)(B)(ii). Regeneron further states that Paragraph 17 contains legal conclusions to which no response is required. Regeneron further states that the BPCIA statute speaks for itself. To the extent that a further response is deemed required, Regeneron denies any remaining allegations of Paragraph 17.

18. Regeneron admits that the BPCIA sets forth a process for resolving patent disputes that may arise with respect to biosimilar products, and that Paragraph 18 quotes portions of 42 U.S.C. § 262(l)(3)(A) and 42 U.S.C. § 262(l)(3)(B)(ii)(I). Regeneron further states that Paragraph 18 contains legal conclusions to which no response is required. Regeneron further states that the BPCIA statute speaks for itself. To the extent that a further response is deemed required, Regeneron denies any remaining allegations of Paragraph 18.

19. Regeneron admits that Paragraph 19 quotes portions of 42 U.S.C. § 262(l)(3)(C). Regeneron further states that the BPCIA statute speaks for itself.

20. Regeneron admits that the BPCIA sets forth a process for resolving patent disputes that may arise with respect to biosimilar products, and that Paragraph 20 quotes portions of 42 U.S.C. § 262(l)(7)(B). Regeneron further states that Paragraph 20 contains legal conclusions to which no response is required. Regeneron further states that the BPCIA statute speaks for itself. To the extent that a further response is deemed required, Regeneron denies any remaining allegations of Paragraph 20.

21. Regeneron admits that the BPCIA sets forth a process for resolving patent disputes that may arise with respect to biosimilar products, and that Paragraph 21 quotes portions of 42 U.S.C. § 262(l)(4)(A). Regeneron further states that Paragraph 21 contains legal

conclusions to which no response is required. Regeneron further states that the BPCIA statute speaks for itself. To the extent that a further response is deemed required, Regeneron denies any remaining allegations of Paragraph 21.

22. Regeneron admits that the BPCIA sets forth a process for resolving patent disputes that may arise with respect to biosimilar products, and that Paragraph 22 quotes portions of 35 U.S.C. § 271(e)(6). Regeneron further states that Paragraph 22 contains legal conclusions to which no response is required. Regeneron further states that the BPCIA statute speaks for itself. To the extent that a further response is deemed required, Regeneron denies any remaining allegations of Paragraph 22.

23. Regeneron admits that the BPCIA sets forth a process for resolving patent disputes that may arise with respect to biosimilar products, and that Paragraph 23 quotes portions of 42 U.S.C. § 262(l)(8). Regeneron further states that Paragraph 23 contains legal conclusions to which no response is required. Regeneron further states that the BPCIA statute speaks for itself. To the extent that a further response is deemed required, Regeneron denies any remaining allegations of Paragraph 23.

24. Regeneron admits that the BPCIA sets forth a process for resolving patent disputes that may arise with respect to biosimilar products. Regeneron further states that Paragraph 24 contains legal conclusions to which no response is required. Regeneron further states that the BPCIA statute speaks for itself. To the extent that a further response is deemed required, Regeneron denies any remaining allegations of Paragraph 24.

THE PARTIES' EXCHANGES PURSUANT TO 42 U.S.C. § 262(l)

25. Regeneron lacks knowledge or information sufficient to form a belief about the truth of the allegations in the first sentence of Paragraph 25, and on that basis, it denies those

allegations. Regeneron admits that on January 5, 2022, Mylan notified Regeneron that Mylan's BLA had been accepted for review by the FDA, and that the parties thereafter began negotiating the terms of access to Mylan's confidential information. To the extent that a further response is required, Regeneron denies any remaining allegations of Paragraph 25.

26. Regeneron admits that it entered into a Confidentiality Agreement with Defendant on or about January 17, 2022, which Regeneron states speaks for itself; that subject to that Confidentiality Agreement, Defendant purported to provide its disclosure of information under 42 U.S.C. § 262(l)(2)(A); and that Defendant gave Regeneron limited access to a database that purportedly contained Defendant's disclosure of information under 42 U.S.C. § 262(l)(2)(A). Regeneron further admits that the database contains more than 1000 documents. Regeneron further states that Paragraph 26 contains legal conclusions to which no response is required. Regeneron denies the remaining allegations of Paragraph 26.

27. Regeneron admits that on February 22, 2022 Regeneron provided a patent list under 42 U.S.C. § 262(l)(3)(A) identifying 29 patents it alleged could reasonably be asserted, noted the limits on its then-current contentions, and subsequently included the '879 Patent in the Complaint. The last sentence of Paragraph 27 is admitted, and the remainder is denied except as expressly admitted.

28. Regeneron admits that it received from Defendant on April 14, 2022, a letter purporting to provide Defendant's detailed statements under 42 U.S.C. § 262(l)(3)(B)(ii)(I) for 28 of the patents on Regeneron's section 262(l)(3)(A) list and purporting to reserve rights to advance additional defenses. Regeneron further states that Paragraph 28 contains legal conclusions to which no response is required. Regeneron denies the remaining allegations of Paragraph 28.

29. Regeneron admits that under 42 U.S.C. § 262(l)(7) it supplemented its section 262(l)(3)(A) list on April 12, 2022, to include U.S. Patent No. 11,299,532; on April 19, 2022, to include U.S. Patent No. 11,306,135; and on May 17, 2022, to include U.S. Patent No. 11,332,771. Regeneron admits that it received from Defendant on May 5, 2022, a letter purporting to provide Defendant's detailed statements under 42 U.S.C. § 262(l)(7)(B) for U.S. Patent Nos. 11,299,532 and 11,306,135, and on June 16, 2022, a letter purporting to provide Defendant's detailed statement under 42 U.S.C. § 262(l)(7)(B) for U.S. Patent No. 11,332,771. Regeneron states that Defendant's letters dated May 5, 2022, and June 16, 2022, speak for themselves. Regeneron denies the remaining allegations of Paragraph 29.

30. Regeneron admits that on June 10, 2022, pursuant to 42 U.S.C. § 262(l)(3)(C), it provided its detailed statement ("*(l)(3)(C)* Statement") describing, on a claim-by-claim basis, the factual and legal basis of Regeneron's opinion that valid, enforceable claims of the patents identified in Mylan's 42 U.S.C. § 262(l)(3)(B)(ii)(I) contentions will be infringed by the commercial marketing of M710, Mylan's proposed biosimilar of Eylea[®]. Regeneron states that its *(l)(3)(C)* Statement and the record before the Patent Trial and Appeal Board ("*PTAB*") speak for themselves. Regeneron denies the remaining allegations of Paragraph 30.

31. To the extent that the allegation of Paragraph 31 seeks to imply that Regeneron was obligated to respond to Mylan's 3(B) Statements directed to the '532, '135 or '771 patents, that allegation is denied. Regeneron admits that it did not provide such statements.

32. Mylan's characterizations of the parties' negotiations are denied, but Regeneron admits that Regeneron proposed that twelve of the patents should be prioritized for litigation, admits that Mylan sought to have Regeneron cease enforcement of its remaining patent rights

altogether, and admits that Regeneron declined to agree to that request. Regeneron denies any remaining allegations of Paragraph 32.

33. Regeneron admits that Mylan notified Regeneron that it intended to identify 25 patents for (I)(6) litigation, with the exception of six of the patents that Regeneron did not contend were presently infringed by Mylan's BLA No. 761274. Regeneron denies the remaining allegations of Paragraph 33.

34. Admitted.

35. Admitted.

COUNT 1

Non-Infringement and Invalidity of U.S. Patent No. 7,070,959

36. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

37. Admitted.

38. Paragraph 38 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 7,070,959.

39. Denied.

40. Denied.

41. Denied.

42. Denied.

COUNT 2

Non-Infringement and Invalidity of U.S. Patent No. 9,222,106

43. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

44. Admitted.

45. Paragraph 45 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 9,222,106.

46. Denied.

47. Denied.

48. Denied.

49. Denied.

COUNT 3

Non-Infringement and Invalidity of U.S. Patent No. 9,254,338

50. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

51. Admitted.

52. Paragraph 52 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 9,254,338.

53. Denied.

54. Denied.

55. Denied.

56. Denied.

57. Denied.

COUNT 4

Non-Infringement and Invalidity of U.S. Patent No. 9,669,069

58. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

59. Admitted.

60. Paragraph 60 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 9,669,069.

61. Denied.

62. Denied.

63. Denied.

64. Denied.

65. Denied.

COUNT 5

Non-Infringement and Invalidity of U.S. Patent No. 9,816,110

66. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

67. Admitted.

68. Paragraph 68 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 9,816,110.

69. Denied.

70. Denied.

71. Denied.

72. Denied.

COUNT 6

Non-Infringement and Invalidity of U.S. Patent No. 10,130,681

73. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

74. Admitted.

75. Paragraph 75 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 10,130,681.

76. Denied.

77. Denied.

78. Denied.

79. Denied.

80. Denied.

COUNT 7

Non-Infringement and Invalidity of U.S. Patent No. 10,406,226

81. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

82. Admitted.

83. Paragraph 83 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 10,406,226.

84. Denied.

85. Denied.

86. Denied.

87. Denied.

COUNT 8

Non-Infringement and Invalidity of U.S. Patent No. 10,415,055

88. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

89. Admitted.

90. Paragraph 90 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 10,415,055.

91. Denied.

92. Denied.

93. Denied.

94. Denied.

COUNT 9

Non-Infringement and Invalidity of U.S. Patent No. 10,464,992

95. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

96. Admitted.

97. Paragraph 97 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 10,464,992.

98. Denied.

99. Denied.

100. Denied.

101. Denied.

COUNT 10
Non-Infringement and Invalidity of U.S. Patent No. 10,669,594

102. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

103. Admitted.

104. Paragraph 104 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 10,669,594.

105. Denied.

106. Denied.

107. Denied.

108. Denied.

COUNT 11

Non-Infringement and Invalidity of U.S. Patent No. 10,857,205

109. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

110. Admitted.

111. Paragraph 111 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 10,857,205.

112. Denied.

113. Denied.

114. Denied.

115. Denied.

116. Denied.

COUNT 12

Non-Infringement and Invalidity of U.S. Patent No. 10,888,601

117. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

118. Admitted.

119. Paragraph 119 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 10,888,601.

120. Denied.

121. Denied.

122. Denied.

123. Denied.

124. Denied.

COUNT 13

Non-Infringement and Invalidity of U.S. Patent No. 10,927,342

125. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

126. Admitted.

127. Paragraph 127 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 10,927,342.

128. Denied.

129. Denied.

130. Denied.

131. Denied.

COUNT 14

Non-Infringement and Invalidity of U.S. Patent No. 10,973,879

132. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

133. Admitted.

134. Paragraph 134 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or

controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 10,973,879.

135. Denied.

136. Denied.

137. Denied.

138. Denied.

COUNT 15

Non-Infringement and Invalidity of U.S. Patent No. 11,053,280

139. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

140. Admitted.

141. Paragraph 141 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 11,053,280.

142. Denied.

143. Denied.

144. Denied.

145. Denied.

COUNT 16

Non-Infringement and Invalidity of U.S. Patent No. 11,066,458

146. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

147. Admitted.

148. Paragraph 148 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No.

11,066,458.

149. Denied.

150. Denied.

151. Denied.

152. Denied.

COUNT 17

Non-Infringement and Invalidity of U.S. Patent No. 11,084,865

153. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

154. Admitted.

155. Paragraph 155 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No.

11,084,865.

156. Denied.

157. Denied.

158. Denied.

159. Denied.

COUNT 18

Non-Infringement and Invalidity of U.S. Patent No. 11,104,715

160. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

161. Admitted.

162. Paragraph 162 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No.

11,104,715.

163. Denied.

164. Denied.

165. Denied.

166. Denied.

COUNT 19

Non-Infringement and Invalidity of U.S. Patent No. 11,174,283

167. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

168. Admitted.

169. Paragraph 169 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No.

11,174,283.

170. Denied.

171. Denied.

172. Denied.

173. Denied.

COUNT 20

Non-Infringement and Invalidity of U.S. Patent No. 11,186,625

174. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

175. Admitted.

176. Paragraph 176 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 11,186,625.

177. Denied.

178. Denied.

179. Denied.

180. Denied.

COUNT 21

Non-Infringement and Invalidity of U.S. Patent No. 11,253,572

181. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

182. Admitted.

183. Paragraph 183 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 11,253,572.

184. Denied.

185. Denied.

186. Denied.

187. Denied.

188. Denied.

COUNT 22

Non-Infringement and Invalidity of U.S. Patent No. 11,299,532

189. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

190. Admitted.

191. Paragraph 191 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 11,299,532.

192. Denied.

193. Denied.

194. Denied.

195. Denied.

COUNT 23

Non-Infringement and Invalidity of U.S. Patent No. 11,306,135

196. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

197. Admitted.

198. Paragraph 198 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or

controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 11,306,135.

199. Denied.

200. Denied.

201. Denied.

202. Denied.

COUNT 24

Non-Infringement and Invalidity of U.S. Patent No. 11,332,771

203. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

204. Admitted.

205. Paragraph 205 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that there is a justiciable case or controversy between Regeneron and Defendant as to the infringement of U.S. Patent No. 11,332,771.

206. Denied.

207. Denied.

208. Denied.

209. Denied.

COUNT 25

Declaratory Judgment of No Lost Profits or Injunctive Relief For Certain Patents

210. Regeneron repeats and reasserts all responses to the preceding paragraphs as if fully stated herein.

211. Paragraph 211 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron denies any remaining allegations of Paragraph 211.¹

212. Paragraph 212 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that Paragraph 212 contains a quotation from a sentence in *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017), which speaks for itself. Regeneron denies any remaining allegations of Paragraph 212.

213. Paragraph 213 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that Paragraph 213 references the BPCIA statute, which speaks for itself.

214. Paragraph 214 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that Paragraph 214 references the BPCIA statute and contains quotations from *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017), which speak for themselves.

215. Paragraph 215 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that Paragraph 215 references the BPCIA statute, which speaks for itself.

¹ Count 25 does not state a claim as a matter of law and is appropriately subject to dismissal. Regeneron, however, will not move to dismiss at this time because Count 25 is outside the scope of the upcoming trial. *See* Dkt. No. 87 (Scheduling Order); Dkt. No. 88 (Regeneron's Stipulation as to Case Narrowing and Injunctive Relief); Dkt. No. 433 (Regeneron's Stipulation Regarding Summary Judgment and Case Narrowing). Regeneron reserves its rights to move to dismiss Count 25 at a later date as appropriate under the Court's Scheduling Order.

216. Paragraph 216 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that Paragraph 216 references and contains quotations from the BPCIA statute, which speaks for itself.

217. Admitted that during the patent dance, Regeneron and Mylan collectively identified a total of twenty-five (25) patents on the lists exchanged pursuant to 42 U.S.C. § 262(l)(5)(B)(i) and that Regeneron filed a lawsuit alleging infringement of the claims of twenty-four (24) of those patents. Regeneron denies any remaining allegations of Paragraph 217.

218. Admitted that on August 5, 2022, Regeneron filed a motion requesting an expedited status conference. Regeneron denies any remaining allegations of Paragraph 218.

219. Admitted that on September 28, 2022, Regeneron indicated to the Court that it was willing to reduce the number of patents for immediate litigation. Regeneron denies any remaining allegations of Paragraph 219.

220. Admitted that Paragraph 220 quotes a statement from Regeneron's counsel, which speaks for itself. Regeneron denies any remaining allegations of Paragraph 220.

221. Admitted.

222. Admitted that on October 25, 2022, the Court entered a Scheduling Order setting a trial for June 2023. Regeneron denies any remaining allegations of Paragraph 222.

223. Admitted that on October 28, 2022, Regeneron filed a stipulation electing six patents from three patent families to proceed in the first stage of litigation. Regeneron denies any remaining allegations of Paragraph 223.

224. Admitted.

225. Denied.

226. Denied.

227. Denied.

228. Denied.

229. Denied.

230. Paragraph 230 contains legal conclusions to which no response is required. To the extent that a response is deemed required, Regeneron admits that a justiciable case or controversy exists between Regeneron and Defendant as to the infringement of U.S. Patent Nos. 7,070,959; 9,222,106; 9,254,338; 9,669,069; 9,816,110; 10,130,681; 10,406,226; 10,415,055; 10,464,992; 10,669,594; 10,857,205; 10,927,342; 10,973,879; 11,066,458; 11,174,283; 11,186,625; 11,306,135; and 11,332,771. Regeneron denies any remaining allegations of Paragraph 230.

231. Denied.

DEFENDANT'S PRAYER FOR RELIEF

Regeneron denies that Defendant is entitled to any remedy or relief whatsoever from Regeneron or the Court, either as prayed for in Defendant's counterclaims or otherwise, and requests that the Court enter judgment in its favor against Defendant and grant the following relief:

- A. A judgment that Defendant is not entitled to any relief under its counterclaims;
- B. A declaration that this is an exceptional case and an award to Regeneron of its attorneys' fees, costs, and expenses under 35 U.S.C. § 285; and
- C. Such other relief as this Court may deem just and proper.

To the extent that paragraphs A–I under Defendant's Prayer for Relief are interpreted to contain any factual allegations, Regeneron denies those allegations.

AFFIRMATIVE AND OTHER DEFENSES

FIRST DEFENSE

Defendant's counterclaims fail to state a claim upon which relief can be granted.

SECOND DEFENSE

Defendant's counterclaims fail to state facts sufficient to entitle Defendant to recovery of attorneys' fees.

THIRD DEFENSE

Defendant's counterclaims fail to state facts sufficient to entitle Defendant to recovery of costs.

FOURTH DEFENSE

The patents asserted in Regeneron's Complaint are not unenforceable.

FIFTH DEFENSE

The patents asserted in Regeneron's Complaint are not invalid.

Date: May 12, 2023

Carey Douglas Kessler & Ruby, PLLC

Of Counsel:

David I. Berl (admitted *PHV*)
Ellen E. Oberwetter (admitted *PHV*)
Thomas S. Fletcher (admitted *PHV*)
Andrew V. Trask (admitted *PHV*)
Teagan J. Gregory (admitted *PHV*)
Shaun P. Mahaffy (admitted *PHV*)
Kathryn Kayali (admitted *PHV*)
Sean M. Douglass (admitted *PHV*)
Arthur J. Argall III (admitted *PHV*)
Adam Pan (admitted *PHV*)
Nicholas Jordan (admitted *PHV*)
Haylee Bernal Anderson (admitted *PHV*)
Renee M. Griffin (admitted *PHV*)
Rebecca Carter (admitted *PHV*)

/s/ Steven R. Ruby
Steven R. Ruby (WVSB No. 10752)
David R. Pogue (WVSB No. 10806)
707 Virginia Street East
901 Chase Tower (25301)
P.O. Box 913
Charleston, West Virginia 25323
(304) 345-1234
sruby@cdkrlaw.com
drpogue@cdkrlaw.com

*Attorneys for Plaintiff Regeneron
Pharmaceuticals, Inc.*

Williams & Connolly LLP
680 Maine Avenue, SW
Washington, DC 20024
(202) 434-5000
dberl@wc.com
eoberwetter@wc.com
tfletcher@wc.com
atrask@wc.com
tgregory@wc.com
smahaffy@wc.com
kkayali@wc.com
sdouglass@wc.com
aargall@wc.com
apan@wc.com
njordan@wc.com
handerson@wc.com
rgriffin@wc.com
rebeccacarter@wc.com

Andrew E. Goldsmith (admitted *PHV*)
Evan T. Leo (admitted *PHV*)
Jacob E. Hartman (admitted *PHV*)
Mary Charlotte Y. Carroll (admitted *PHV*)
Sven E. Henningson (admitted *PHV*)
KELLOGG, HANSEN, TODD, FIGEL &
FREDERICK, P.L.L.C.
1615 M Street, NW, Suite 400
Washington, DC 20036
(202) 326-7900
agoldsmith@kellogghansen.com
eleo@kellogghansen.com
jhartman@kellogghansen.com
mcarroll@kellogghansen.com
shenningson@kellogghansen.com

*Attorneys for Plaintiff Regeneron
Pharmaceuticals, Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on May 12, 2023, I electronically filed the foregoing with the Clerk of the Court by using the Court's CM/ECF system. Counsel of record for all parties will be served by the Court's CM/ECF system.

/s/ Steven R. Ruby

Steven R. Ruby